

8.0 Special 510 (k) Summary

510 (k) Summary
Summary of Safety and Effectiveness Information
Supporting a Substantially Equivalent Determination

The Product

- SynVibro Flush Cat.No. 1584

Indications for use:

SynVibro Flush is used for retrieval and washing of human oocytes and holding throughout oocytes recovery.

The product formulation:

Earl's Balanced Salt Solution (EBSS)

Sodium Pyruvate

Assisted Reproduction Technology Supplement (ARTS)

HEPES

Sodium Bicarbonate

Product testing control contents:

Sterility test

pH

Osmolality

Endotoxin: ≤ 0.10 EU / ml (LAL-test)

Mouse Embryo Assay (Two-cell assay, Blastocyst rate: $> 80\%$)

Note: The results for each batch are stated on a Certificate Of Analysis, which is available upon request.

Stability and Biocompatibility testing

All data obtained in the present stability study indicate that SynVibro Flush was stable up to 16 weeks after production.

Furthermore SynVibro Flush was Classified as non toxic according to the Mouse Embryo Test , non-irritant according to vaginal irritation test and showed no evidence of delayed contact hypersensitivity .

Clinical Documentation:

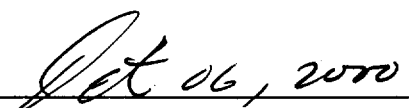
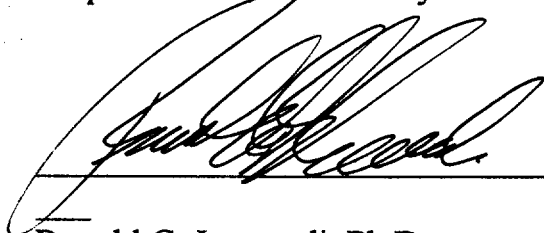
SynVibro Flush has been compared to the HSA containing Flushing Medium (K 991327) in a randomised prospective multi-centric study in Denmark.

The study included 107 IVF / ICSI cycles and a maximum of 2 embryos was replaced in each group with the exception of 3 cases where 3 embryos were replaced. No adverse experiences were noted during the oocyte recovery in any of the two groups. The pregnancy rate per completed cycle and the implantation rate per embryo replaced were similar in both groups. (S. Ziebe et al. ESHRE 2000, Bologna, Italy. O - 0185, p.74.).

SynVibro Flush was marketed in Europe in March 2000. There have been no registered complaints on the product and no evidence that the product has been the cause of any serious adverse events in connection with its intended use.

Thus based on the clinical data presented we feel that the safety and effectiveness of the product for its intended use is shown in the present submission and the products is substantially equivalent to the predicated device Medi-Cult's Flushing Medium (K 991327)

Prepared and Submitted by:



Ronald G. Leonardi, Ph.D.
President
R & R REGISTRATIONS
P.O. Box 262069 San Diego, Ca 92131
858-586-0751

Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 22 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medi-Cult a/s
c/o Ronald G. Leonardi, Ph.D.
President
R & R Registrations
P.O. Box 262069
SAN DIEGO CA 92196-2069

Re: K003163
SynVibro Flush
Dated: December 26, 2000
Received: December 28, 2000
Regulatory Class: II
21 CFR §884.6180/Procode: 85 MQL

Dear Dr. Leonardi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known) K003163

K

Device Name: Syn Vitro Flush

Indications for Use:

SynVitro Flush is used for retrieval and washing of human oocytes and holding throughout oocyte recovery.

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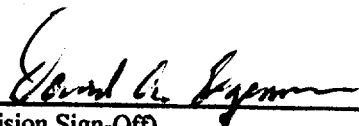
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
 Use ☐
 (Per 21 CFR 801.109)

OR

Over-The-Counter

(Optional Format 1-2-96)


(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003163